DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/01/2008 has been entered.

2. Currently, claims 74-78 are pending in the instant application. Claims 1-73 have been canceled and claim 77-78 has been added. This action is written in response to applicant's correspondence submitted 02/01/2008. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

3. The rejection of claims 74-77 under 35 USC 112, 1st paragraph made in section of the office mailed 11/02/2007 has been withdrawn in view of the amendment to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 74-76 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Okamoto et al. (US Patent 6476215 Nov 2002).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to claim 74, Okamoto et al. teach a preparing a substrate containing three different probes by bubble jet printing followed by hybridization of ssDNA complementary to the probe and detection by fluorescence microscopy (see column 2 lines 36-60, and example 8, column 24, lines 15 through column 26 line 26). Okamoto et al. teach a substrate with square sections and individual spots to define a matrix with samples having different properties (see column 14, lines 1-7). Okamato et al. teach application of two test samples (1 μM ssDNA) and spotted on the array and subject to hybridization. Okamoto et al. teach application of 1 μM ssDNA with a base sequence complementary to DNA of SEQ ID No. 1 (18 base pairs) (second

sample) nucleic acids for hybridization reaction (see example 2 and example 8) (spotting predetermined liquid amount of each test sample in each section in such a manner that individual spots in each section are spaced to conduct a complex forming reaction). Okamato et al. teach the respective spots were observed by microscopy (detecting whether a complex formed and is present or not in each spot).

With regard to claim 75-76, Okamoto et al. teach application of samples by ink-jet method. Okamoto et al. teach using a bubble jet method (see column 15, lines 29-31).

With regard to claim 78, Okamoto et al. teach a density of 400/cm^2 (see column 14, lines 30-35 and 51-64).

6. Claims 74-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (US Patent 6893816)

With regard to claim 74, Beattie et al. teach a method for conducting a multiplicity of individual and simultaneous binding reactions which comprises a substrate that is microfabricated with a set of discrete and isolated region correspond to location of binding reaction and each discrete region contains a sample of a biomolecules of discrete chemical structure fixed to such bounded region and upon contact with substrate and sample containing one or more molecule species (spotting a predetermined liquid amount of each of the test sample in each section in such a manner that individual spots are spaced in order to conduct a reaction) the detection of bounded region in which binding has taken places yields a pattern of binding capable of characterizing or identifying the molecular species in the test sample(detecting whether a complex formed between the oligonucleotide and object component is present) (see column 2 lines 1-20). Beattie et al. teach preparing a detection substrate with a plurality of

square sections with individual spots (see figure 3 and example 3). Beattie et al. teach PCR products (preparing a detection substrate having plurality of square section in each spot) are applied to individual wells using a dispensing head. Beattie et al. teach hybridization of cytoplasmic RNA to identical cDNA arrays (spotting predetermined liquid amount of each sample to each section to conduct a complex forming reaction) to yield two hybridization patterns and detection of hybridization by phosphorimager (see example 11).

With regard to claim 75-76, Beattie et al. teach using inkjet technology as a microdispensing method for fluid volume is employed (see column 14, lines 30-50).

Maintained Rejections

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 74-75 and 77-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US Patent 5807522 Sep. 1998). This rejection was previously presented and has been rewritten to address the newly submitted claims 77-78.

With regard to claims 74-75, Brown et al. teach a method of detecting differential expression of each of a plurality of genes in a first cell type with respect to expression of the same genes in a second cell type (see column 4, lines 52-59). Brown et al. teach mixtures of labeled cDNA from the two cell types is added to an array of polynucleotides representing a plurality of known genes (component from at least two liquid test samples) (see column 4, lines

60-63). Brown et al. teach the array is examined by fluorescence to determine the relative expression of known genes in the two cell types by each spot (determining whether the object component is contained in each of the two liquid test samples) (see column 4, lines 64-67 and column 5, lines 1-5). Brown et al. spotting polynucleotides of about 50 bp on the array surface and a small volume of labeled DNA probe mixture (at least two liquid test samples) in a standard hybridization solution is loaded onto each cell and incubation at appropriate temperatures for hybridization by reaction with detection reagents and analyzed using calorimetric, radioactive, or fluorescent detection (see column 13, lines 10-46). Brown et al. teach 100 DNA fragments representing all known mutations of a given gene fabricated on an array (fixing plural types of oligonucleotides having known base sequence different from one another). Brown et al. teach an array of regions on a solid support comprising a two dimensional array with discrete regions having a finite area (see column 6, lines 29-32) and teach the 96 cell array is about 1 to 30 mm in width and 1 to 50 mm in length (claim 77) (see column 11, lines 62-67). Brown et al. teach an array of regions having a density of at least about $100/cm^2$, thus the square section is 400 oligonucleotides per centimeter square or less. (see column 6 lines 33-35). Brown et al. teach the array is formed in a plurality of analyte-specific reagent regions, each region may include a different analyte-specific reagent and teach the 96 microarrays assayed with 96 patient samples are incubated, rinsed, detected, and analyzed using standard calorimetric, radioactive, or fluorescent detection and teaches the process can be reversed where the patient or organism's DNA is immobilized as the array elements and each array is hybridized with a different mutated allele or genetic marker (claim 75) (see column 15, lines 18-51).

Response to Arguments

9. The response traverses the rejection on page of the response mailed 02/01/2008. The response asserts that Brown does not suggest spotting a predetermined liquid amount of each of the test samples in each section in such a manner that individual spots are sufficiently spaced from each other to conduct a complex-forming reaction between the oligonucleotide and the object component in each spot. The response asserts that it is schematically demonstrated in figure B of the response filed 08/14/2007. This response has been thoroughly reviewed but not found persuasive. The claims require spotting a test sample in each square section such that individual spots are sufficiently spaced from each other to conduct a complex –forming reaction. The claims are not limited nor require that each test sample is spotted separately or that spots are not contact with each other, as depicted in figure A submitted on by the response 08/14/2007, the claims merely require that two test samples at a predetermined liquid amount are spotted in the square section and require that the individual spots, which could encompass the entire substrate or square, are sufficiently spaced in order to conduct a complex-forming reaction between the oligonucleotides and the object component in each spot, as depicted in figure B submitted on 08/14/2007. As such, Brown et al. teach spotting a predetermined liquid amount of two test samples, Brown et al. teach cDNA products from wild type Arabidopsis and transgenic line of Arabidopsis are spotted together on an array in 10 microliter hybridization reaction. Brown et al. teach detection of HAT4 gene in the transgenic line but not wild type Arabidopsis and therefore Brown et al. teach the spotting of the predetermined liquid amount of the two test samples were sufficiently spaced in order to conduct a complex forming reaction (see example 2, column 17, lines 55-67 and column 18 lines 5-17).

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

10. Claims 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Southern et al. (US Patent 5700637 published Dec. 23 1997). This rejection was previously presented in section 7 of the office action mailed 05/16/2007 and is reiterated below.

With regard to claim 74-76, Southern et al. teach an apparatus and method for analyzing a polynucleotide sequence of a known or unknown sequence. Southern et al. teach an apparatus comprising a support and attached to the surface a complete set of oligonucleotides of chosen lengths occupying separate cells and being capable of taking part in hybridization reactions (object component capable of binding to the oligonucleotide) (see column 1, lines 35-47). Southern et al. teach the use of a support by applying labeled material under hybridization conditions to the array to observe the location of the label on the surface associated with particular members of the oligonucleotides (see column 1, lines 52-60). Southern et al. teach preparing a substrate with a plurality of regions (squares) and teaches stripes that 1mm long (side length) (see column 14, lines 48-50). Southern et al. teach the spots can be laid down with a low cost ink jet printer (see column 6, lines 53-56) (claim 76). Southern et al. teach that adding a plurality of oligonucleotides with two different bases in a rectangular patch on the substrate (fixing plural types of oligonucleotides having known base sequences different from one another and present at a uniform surface density in each section) (claim 75) (see column 10, lines 1-6 and example 3). Southern et al. teach preparing clinical samples of three different DNA samples and applying these probes in liquid sample to the surface carrying six oligonucleotide strips and

detecting the hybridization signal (detecting whether a complex formed between the oligonucleotide and object component) (see column 12, lines 1-23, example 6).

Response to Arguments

11. The response traverses the rejection on page 6 of the response mailed 02/01/2008. The response asserts that Southern does not spot a predetermined liquid amount of each of the test samples in each section in such a manner that individual spots are sufficiently spaced from each other to conduct a complex-forming reaction between the oligonucleotide and the object component in each spot. This response has been thoroughly reviewed but not found persuasive. The claims are not limited to the spots that are not in contact with each other nor do the claims require that each test sample is spotted in individual spots separately and thus not be in contact with each other. The claims merely require spotting a predetermined liquid amount of the two test samples in each square section of the substrate so that the spots are sufficiently spaced from each other to conduct a complex forming reaction. The claims do not require that each test sample is individually spotted and not contacting each other nor do the claims require spotting the test samples at different locations within the square section. Furthermore, the spots can encompass the entire square section or the entire substrate; the claims do not limit the type of spot. Therefore, Southern et al. anticipates the claimed invention as Southern et al. teach preparing clinical samples of three different DNA samples and spotting these probes in liquid sample to the surface carrying six oligonucleotide strips and detecting the hybridization signal, wherein detecting the hybridization signal indicates that the spots are sufficiently spaced from each other to conduct a complex forming reaction (see column 12, lines 1-23, example 6).

For these reasons, and the reasons made of record in the previous office actions, the rejections are maintained.

Conclusion

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAE BAUSCH whose telephone number is (571)272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Sarae Bausch/
Primary Examiner, Art Unit 1634